

§ 520.2605

21 CFR Ch. I (4-1-02 Edition)

tonsillitis, acute upper respiratory infections and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.¹

(2) The drug is administered orally at an initial dosage level of ½ tablet twice daily to dogs weighing up to 10 pounds, one tablet twice daily to dogs weighing 11 to 20 pounds, two tablets twice daily to dogs weighing 21 to 40 pounds, and three tablets twice daily to dogs weighing over 40 pounds. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.¹

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.¹

(4) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.¹

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2605 Trimeprazine tartrate and prednisolone capsules.

(a) *Specifications.* Each capsule contains 3.75 milligrams of trimeprazine in sustained released form (as the tartrate) and 1 milligram of prednisolone (capsule no. 1) or 7.5 milligrams of trimeprazine in sustained release form

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(as the tartrate) and 2 milligrams of prednisolone (capsule no. 2).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer either capsule orally once daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 2
Up to 10	1
11 to 20	2	1
21 to 40	4	2
Over 40	6	3

(2) *Indications for use.* For the relief of itching regardless of cause, reduction of inflammation commonly associated with most skin disorders of dogs such as eczema caused by internal disorders, otitis, and dermatitis (allergic, parasitic, pustular, and nonspecific). It is also used in dogs as adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, tonsillitis, acute upper respiratory infections, and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

(3) *Limitations.* After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained. Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 19367, Apr. 29, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]